

### ENZYMATIC THERADY INCORPORATED

What Better feels like." June 25, 2004

#### INTEGRATIVE THERAPEUTICS INC."

NF Formulas » PhytoPharmica Tyler Encapsulations + Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 + F: 503.582.0467

## **ENZYMATIC THERAPY** PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 \* F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

JUL 21

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Fiber Fusion™ Daily Cleansing Fiber*	Safe, Natural and Effective!*	Psyllium Husk 95% USP, Raftiose Synergy 1, Natural Rasberry Flavor, Rasberry Powder Freeze Dry, Citric Acid Fine USP, Syloid 244 FP, Glycerine USP Natural, Stevia Extract 90%, Mag-nifique (Flavor Masking Agent)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: <u>(,/</u>25/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Chief Financial Officer

Fiber Fusion 11e

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## ENZYMATIC THERAPY

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June 24, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE
·		CLAIM REFERS
Fiber Fusion™	A great source of	Psyllium Husk 95% USP, Raftiose
Daily Cleansing Fiber*	roughage for those living	Synergy 1, Natural Rasberry
	the low-carb lifestyle.*	Flavor, Rasberry Powder Freeze
		Dry, Citric Acid Fine USP, Syloid
		244 FP, Glycerine USP Natural,
		Stevia Extract 90%, Mag-nifique
		(Flavor Masking Agent)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/24/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Chief Financial Officer

Fiber-Eusion 10e



## ENZYMATIC THERADY

INCORPORATED

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE
Fiber Fusion™ Daily Cleansing Fiber*	Fiber Fusion™ Daily Cleansing Fiber* is a great way to keep your digestive system cleansed and regular on a daily basis.*	CLAIM REFERS  Psyllium Husk 95% USP, Raftiose Synergy 1, Natural Rasberry Flavor, Rasberry Powder Freeze Dry, Citric Acid Fine USP, Syloid 244 FP, Glycerine USP Natural, Stevia Extract 90%, Mag-nifique (Flavor Masking Agent)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 6/23/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Chief Financial Officer

Fiber-Fusion 9e